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The Dissemination of Local Health Innovations: Political Economy Issues in Brazil

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Introduction

In a book exploring the scope for mutually supportive integration between addressing health care needs and promoting industrialization, Brazil's experience offers an important case study.¹ This chapter presents Brazil's main strategies to ensure access to medicines to tackle the population's principal health problems. It particularly aims to show how the principle of the universality of care has influenced industrial policies and production in the pharmaceutical sector. Although more than 25 years have passed since Unified Health System (*Sistema Único de Saúde*: SUS) was established, and much progress has been made, a great many challenges remain. This chapter focuses particularly on those related to access to health technologies.

The underlying premise of the Brazilian approach is that health is a social right and improving the health of individuals has a positive impact on society as a whole. Yet the sustainability of the health system depends on a domestic production system capable of producing the needed technologies for health care. That production system in turn constitutes an important economic sector, generating employment and income and capable of reducing external dependence in strategic areas. This chapter explores how this relationship is configured within Brazilian society, the progress made and challenges faced by attempts to guarantee a reduction in health inequalities, with the aim of increasing policy dialogue between Brazilian, African and other policy makers and researchers. Brazilian experience in the dissemination of local innovations to meet health needs could be learned from and drawn upon by other countries, including recognition of the huge challenges that remain.

New medical technologies hold great promise for improvements to the population's health, but they accentuate concerns about the amplification of already significant health inequalities, since their consumption is determined by a range of factors, including the socio-economic status of the patient and the existence of public systems that guarantee patient access (Goldman and Smith, 2005). The impact of new technologies on health disparities depends on how hard they are to adopt and who effectively receives treatment. They are not uniformly absorbed into health systems, nor is there a guarantee of access for all, even in systems with universal coverage (Loureiro et al., 2007).

In high-income countries, research and development (R&D) efforts may result in innovations driven by technology, despite a high degree of uncertainty. However, in developing countries, demand constitutes the principal stimulus for innovation. From this perspective, the legal framework and the organization of health systems may either direct the diffusion of technologies towards social interests or allow the process to occur in a manner more closely aligned with market interests.

For its part, health care is increasingly expensive and dependent on a series of technologies such as diagnostic and surgical equipment and pharmaceutical products. The factors responsible for significant increases in health spending as a proportion of a country's domestic income and which may compromise the sustainability of its health system, include: the cumulative nature of the use of medical technologies; the oligopolistic structure of the sector, which often includes temporary monopolies obtained via intellectual protection; increases in per capita income and life expectancy; and changes to the epidemiological profile.

The sustainability of health systems is therefore one of the greatest challenges for public administrations at a global level, particularly for countries with universal systems such as Brazil, a middle-income country. Since 1988, the Brazilian state has considered health as a right and its provision as a duty that must be guaranteed to all its citizens; this includes pharmaceutical health care, which is considered necessary for the guarantee of comprehensive services.

Given significant pressure for the systematic incorporation of new medicines into the Brazilian health system, the country has sought to incentivize the growth of domestic technological capability, reflecting the demands of its Unified Health System. From this perspective, innovation within this industry has significant relevance for Brazil's social and economic development and presents huge challenges, given the complexity of scientific and technological development activities, the political and institutional coordination required, the scarcity of

resources and the nature of mechanisms for knowledge production and appropriation.

This is, therefore, a field that allies economic dimensions with a strong social dimension, requiring the mobilization of a broad regulatory and institutional apparatus. In this way, despite the crisis in the both the Keynesian and the welfare state, health continues to be one of the most significant areas of state intervention, both in the service sector and in scientific and technological activities (Aragão et al., 2014; Gadelha and Costa, 2012).

Pharmaceutical health care in Brazil: seeking to link economic and social logic

The logic of social rights

The Unified Health System (SUS) was instituted by the 1988 Federal Constitution, as a result of a widespread movement for the democratization of society and another within the health sector, known as Sanitary Reform, which sought to create a public health system for all the country's citizens (Paim, 2009). Since 1988, health has been considered an inalienable right, and the state is responsible for guaranteeing universal, comprehensive and equitable access to activities and services that include the prevention of diseases and the promotion and restoration of health.

Through the 1988 Federal Constitution, the health system was integrated into the social security system and the social care and welfare systems (Federal Constitution 1988, art. 194), becoming a sector without restrictions on beneficiaries, where access did not require users' contribution (Brasil, 1998, art. 196).

The interpretation of the concept of social justice in the Brazilian Federal Constitution is innovative, since it views social security as 'an integrated series of activities initiated by the public authorities and by society, aimed at security rights related to health, welfare and social care',² introducing the notion of universal social rights as a condition of citizenship. It recognizes social rights and asserts that it is the duty of the state to guarantee such rights.

In the case of the SUS, universality represents the opportunity for all citizens to use public health activities or services without barriers to access of an economic, physical or cultural nature; comprehensiveness is understood in relation to a series of coordinated and continuous preventative and curative, individual and collective activities and services, at all levels of system complexity; and equity contains within it a

certain notion of justice. It recognizes that individuals are different from each other, and therefore deserve differentiated treatment. In this sense, access to medicines begins to constitute a right, in that it is a health care component at all levels of complexity.

The 1990 Organic Health Law (*Lei Orgânica da Saúde*: LOS) asserts that the execution of comprehensive therapeutic care activities falls to SUS, and this includes pharmaceutical health care, given that medicine is a strategic ingredient to support health activities and its absence may compromise treatment, affecting both the patient's quality of life and the problem-solving capacity of health activities.

To secure this, it is envisaged that the SUS, amongst other bodies, formulates public policies; develops programmes that enable the population's access to medicines, equipment, vaccines and other supplies to meet its health needs; and participates in their production, either directly through public laboratories, or indirectly, acting jointly with those economic and science and technology bodies aimed at guiding research, development and production in the public interest. Furthermore, it operates through agreements and partnerships with private pharmacies, enlarging distribution channels. This is regarded as a tense arena of negotiation between collective and private interests, highlighting the need for state action to ensure that the institutional framework functions adequately (Gadelha, 2006; Gadelha et al., 2012; Oliveira et al., 2006).

Brazilian pharmaceutical health care policy

The integration of pharmaceutical management with production policy is distinctive of the Brazilian approach. To secure its guarantee to supply medicines to the Brazilian population, the Ministry of Health needed to work with, amongst others, the economic and science and technology spheres as core elements in the conduct of policies that guarantee the production of pharmaceutical products designed to meet SUS needs.

Although the right to pharmaceutical health care has been enshrined in the SUS since its creation, a specific policy – the National Medicine Policy (*Política Nacional de Medicamentos*: PNM) – was only created in 1998. In 2004, this was superseded by the National Policy of Pharmaceutical Care (*Política Nacional de Assistência Farmacêutica*: PNAF) (Brasil, 2004a). Overall, this strategy extends the Brazilian population's access to medicines and is therefore based on the same principles that guide SUS. This policy is based on the promotion of the rational use of medicines. It includes a range of adjustments to pharmacy practices and

regulation, the production of essential medicines and scientific and technological development. Thus several initiatives were taken to enhance the national production of pharmaceutical drugs such as qualifying the public laboratories, and incentives to private groups to produce priority drugs to meet the SUS demand with financial support from distinct governmental agencies and offices other than the health sector.

The financing of public pharmaceutical health care programmes is the responsibility of the three spheres of SUS management: the federal, state and municipal governments. The allocation of resources to finance the acquisition of medicines and supplies is organized into three pharmaceutical health care components: basic, strategic and specialized. Each component includes resources for financing one or more programmes or activities, and each has its own features related to planning and administration. Medicines for HIV/AIDS, cancer and coagulopathy are not included within any of these components, but are funded exclusively by the federal government.

The federal government also bears the cost of supplying medicines through the Brazilian Popular Pharmacy (*Programa Farmácia Popular do Brasil*: PFPB) and the *Here There Is a Popular Pharmacy* (*Aqui Tem Farmácia Popular*) programmes (described below), which provide certain medicines either free of charge or at low cost, making them more accessible to the population (Brasil, 2004b).

Links to technological development in medicines

With the implementation of the PNM, Brazil expanded a strategic project for the technological development of medicines, initially through public production of essential medicines by laboratories belonging to the SUS (currently 19 SUS public laboratories). Two notable health policies in this initial period were investments by the Ministry of Health to allow public laboratories to produce less-expensive versions of anti-retroviral drugs, beginning in 1996, and the implementation of the Generic Medicines Law in 1999.

Brazil's policy of universal access to free anti-retroviral treatment supplied directly to the public sector has been in force since 1996, and has been an exemplary model for global efforts to reduce the HIV epidemic. However, it has also involved a significant increase in Ministry of Health spending on medicines, which rose from approximately US\$35 million in 1997 to a landmark US\$305 million in 1999 (Loyola, 2008). The vast majority of these medicines were imported, implying that fluctuations in the dollar led to interruptions in supply. The response was investment in the domestic production of medicines.

This initiative inaugurated the systematic establishment of agreements between the public and private sectors for the transfer of technology to public laboratories that manufacture medicines. Currently, the country is capable of producing 10 of the 23 medicines that constitute the HIV/AIDS treatment cocktail. Farmanguinhos alone, the Oswaldo Cruz Foundation (FIOCRUZ) Laboratory and part of the Ministry of Health, produces and distributes seven of the ten anti-retroviral drugs produced in the country (Fiocruz, 2014). FIOCRUZ is the largest public health institution in the country, for research, education, health care, development and pharmaceutical drugs production. Farmanguinhos is the unit for the production of pharmaceutical chemicals, and Biomanguinhos for the production of biologicals. These units, like others public laboratories, supply the specific programmes of the Ministry of Health.

The Generic Medicines Law enabled competition on the part of the public and private domestic industry in the market for drugs with expired patents. On the other hand, from 1996 onwards, the Patent Law (1996) recognized pharmaceutical patents in Brazil by adhering to the Trade-Related Aspects of Intellectual Property Rights (TRIPS). This had a negative impact on the domestic industry, one of whose competitive pillars was the commercialization of similar medicines (copies of the branded drugs) and which could not compete with the large international oligopolies in the production of innovative medicines. The domestic market configuration changed as a result. National companies focussed on the production of generic versions and multinationals increased their share in reference products that are more expensive than generic versions (Capanema and Palmeira, 2004; Gomes et al., 2014)

Strengthening industrial policy for pharmaceuticals

However, the right to pharmaceutical assistance within the SUS and the need to provide essential products to the Brazilian population at accessible prices required a series of measures to strengthen the pharmaceutical industry in Brazil, particularly in sectors serving the principal public health requirements. In the face of these challenges, the strengthening of the pharmaceutical chain became a strategic objective of Brazil's industrial and development policies.

Several public bodies, including the National Development Bank (*Banco Nacional de Desenvolvimento*: BNDES), started to support the development of the country's pharmaceutical chain. The Support Program for the Development of the Pharmaceutical Productive Chain (*Programa de*

Apoio à Cadeia Farmacêutica: ROFARMA), launched in 2004, provided specific BNDES credit support to contribute to growth in the domestic pharmaceutical industry.

Between 2004 and 2013, BNDES invested almost 5 billion Brazilian Reals in approximately 110 operations, spread across lines of support aimed at production, innovation, restructuring and biotechnology, and focusing on domestically owned companies and public laboratories. In its first phase, PROFARMA constituted an important source of funds to ensure that the national pharmaceutical complex complied with the new regulatory demands, which had become much more rigorous after the 1999 creation of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*: ANVISA). However, throughout its existence, the programme adapted to industry needs, focusing on the production of generic medicines, on innovation and on the development of biotechnology, due to the increasing application of biopharmaceuticals in the treatment strategies for a range of diseases, particularly chronic non-communicable illnesses (Palmeira Filho et al., 2012).

These and other initiatives resulted in increased investment in research and development (R&D) within the Brazilian pharmaceutical industry. According to the Survey of Technological Innovation (*Pesquisa de Inovação*: PINTEC), in 2003, R&D investment by the pharmaceutical industry corresponded to 0.5% of net revenue, slightly lower than industrial sector average. In 2011, this had risen to 2.4% of net revenue, while the average for the industrial sector remained at around 0.7% (PINTEC/IBGE, 2011).

Local production for domestic requirements

The combination of the legal framework and the SUS organizational system has sought to direct the diffusion of technologies towards social interests, rather than allowing the process to occur in a manner aligned only with market interests. The data show that the investments in the pharmaceutical supply chain have been reflected in the consolidation of the local generic medicine sector. Since 2004, the total pharmaceutical market in Brazil has grown exponentially, both in number of units sold (9% per annum) and in real value (10% per annum), reaching almost R\$ 40 billion in 2013 (Gomes et al., 2014; Interfarma, 2014). The market for generic medicines has provided a significant element of this growth, since in terms of unit sales, generic drugs' share of total sales leapt from 9% in 2004 to 27% in 2013 (Figure 9.1), while sales of both brand-name drugs and similar drugs fell (Gomes et al., 2014; Kaplan et al., 2013).

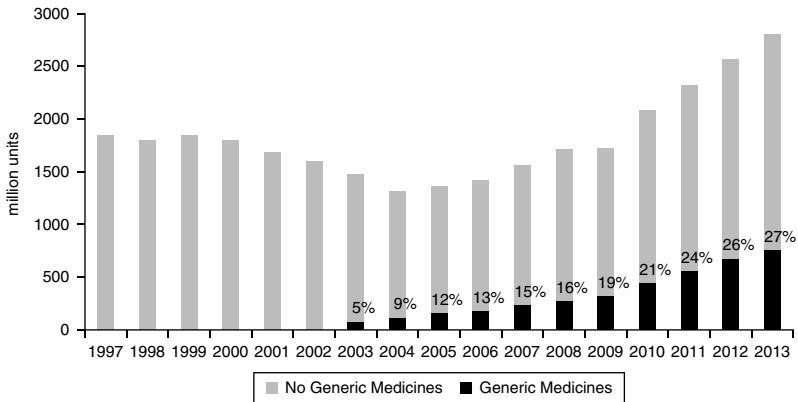


Figure 9.1 The Brazilian pharmaceutical market (unit sales), 1997–2013

Source: Drawn by the authors from data sourced from Progenericos (2014) and Gomes et al. (2014).

As the Gomes et al. (2014) study points out, the opportunities generated by the dynamism of the internal market, increasing improvements to sanitary regulation in Brazil and public policies have all been exploited by domestically owned companies, whose domestic market share rose from 30% at the beginning of the 2000s to over 50% in 2012.

In 2013, five Brazilian pharmaceutical companies were among the ten biggest companies in the Brazilian national market, measured by total sales. Generic drugs had almost 30% of the Brazilian market, measured in units sold, 15% by total sales. Furthermore, 85% of the drugs available in the Popular Pharmacy Program are generic drugs. As regards the origin and ownership of the capital invested, about 90% of the companies producing generic drugs are Brazilian, 6.3% are from India, 0.8% from Germany, 0.6% are Canadian and 0.5% Spanish (Progenericos, 2014).

The share of household income spent on medicines is higher in Brazil for those on lower incomes. Medicines account for 4.2% of spending in households with a monthly income of up to US\$452.20. This corresponds to 76.4% of health expenditure for households within this income bracket. For those with a monthly income over US\$5,655.20, spending on medicines is only 1.9% of income (IBGE-POF, 2008–09). Therefore, the SUS is a decisive instrument for the reduction of inequalities, in coordination with the economic and science and technology fields, and for the promotion of health as a priority for the sustainable development of the country (Gadelha et al, 2014).

Public demand and domestic medicines production

The enlargement of the state's purchasing power has been a fundamental strategy for extending access to medicines and strengthening the production base to address SUS interests, both public and private. Out of a range of important inter-sectoral initiatives (Aragão et al., 2014; Gadelha and Costa, 2012), two programmes particularly help to understand how current initiatives to strengthen the health sector in Brazil have had an impact on the domestic production of medicines.

The first, the Brazilian Popular Pharmacy Programme (*Programa Farmácia Popular do Brasil*: PFPB), was established in 2004 within the Ministry of Health in order to extend the population's access to essential medicines. It was hugely important in the growth of the generic medicines sector in Brazil, since its establishment relied heavily on the extension of the domestic production base. The second, the Partnerships for Productive Development (*Parcerias para o Desenvolvimento Produtivo*: PDPs), begun in 2012, aimed to strengthen the domestic pharma-chemical and medicine industries, particularly in more innovative areas such as biotechnology, in order to reduce external dependence in key strategic areas.

Industrial policy in Brazil generally recognizes the potential of public procurement to promote competition in markets where government demand is significant, such as health. Rules have been defined for the use of public purchasing power, which allow a price preference of up to 25% for purchases from domestic producers, using a method of calculation that takes into account employment and income generation, impact on tax revenues, national development and other factors.³

The Brazilian Popular Pharmacy Programme (PFPB)

The PFPB expanded access to medication for the most common diseases, benefitting people on low incomes and enabling access to low-cost medicines for users of the private health network. Federal government initiatives included centralization of the medicines procurement and administrative improvements. Medicines were acquired, distributed and managed centrally by FIOCRUZ, a unit of the Ministry of Health. This procurement strategy was underpinned by a guarantee of state funding.

In order to meet the pharmaco-therapeutic needs of PFPB users, the Ministry of Health established a list of medicines based on the National Essential Medicines List, which was defined using epidemiological criteria, taking into account the principal diseases that affect the Brazilian population and the treatments that have the greatest impact

on household budgets. The list also considers the medicines contained within the Ministry of Health's Welfare Programmes, the production capacity of the Official Pharmaceutical Laboratories and registration as a generic medicine (Brasil, 2005; 2010).

Initially restricted to the SUS network, from 2006 the Programme was extended to the private sector through partnerships with pharmacies. In 2011, with the launch of the Brazil Without Extreme Poverty Plan (*Plano Brasil Sem Miséria*), the municipalities included in this plan to eradicate extreme poverty were prioritized by the PFPB, in line with criteria adopted by the Ministry of Social Development and Combating Hunger.

Given the country's epidemiological profile, one programme priority is to extend access to hypertension and diabetes medication. About 33 million Brazilians have been diagnosed with hypertension and 80% (or approximately 22.6 million hypertension sufferers) are treated within the public health network. According to 2011 data, more than 7.5 million Brazilians have a diabetes diagnosis and about 6 million of these patients are treated within the public system. These diseases are included in the risk factors for cardiovascular problems, the greatest cause of mortality in Brazil (WHO, 2012). Through the activities of the PFPB aimed at non-communicable diseases (NCDs), medicines for the treatment of hypertension, diabetes and, latterly, asthma began to be dispensed to patients free of charge. In 2011, respiratory diseases were the third cause of death in the country (MS/PFPB, 2014; WHO, 2012).

Currently, the PFPB provides access to essential medicines for a wide range of patients with a private medical prescription, complementary to SUS, at low cost or free of charge. The initial list of medicines included 84 pharmaceuticals, dispensed to the population using their generic names, representing more than 1,200 commercial medicine brands registered in the pharmaceutical market. The PFPB provides for the inclusion of new products and takes into account regional variations, given its territorial coverage and the diversity of the epidemiological profiles across the different regions of the country. The first additions to the PFPB list of medicines occurred in 2004, when seven new items were added. Since then, new updates to the list have been made in order to increase its coverage. By 2013, more than 550 medicines had been made available (Brasil, 2004b; MS/PFPB, 2014).

It is worth noting that the products distributed through the PFPB are acquired through specific procurement processes, not to be confused with public procurement by federal, state, federal district and municipal governments. The programme prioritizes purchase of medicines

produced by official government laboratories (public industrial units) and generic medicines (acquired through a bidding process); a pharmaceutical's availability as a generic medicine is therefore a factor for inclusion into the PFPB medicine selection process.

The expansion of the PFPB budget, of the accredited network and of the number of municipalities served has both reflected demand and coincided with growth in the generics market in Brazil (Figure 9.2).

By March 2015, more than 33,000 establishments had been accredited by the PFPB, distributed across 4,351 of the 5,570 Brazilian municipalities and providing almost 80% coverage in municipalities with Popular Pharmacy establishments. This is in contrast to 2006, when 2,955 establishments were accredited in 594 municipalities, with coverage of only 11% of municipalities. To this end, the programme's budget has increased significantly over the years.

Federal spending on the PFPB, in real terms in 2013 prices, has jumped from a little over R\$35.7 million in 2006 to R\$879.5 million in 2011, R\$1.4 billion in 2012 and R\$1.9 billion in 2013. In 2013, total spending on medicines rose to slightly over R\$10 billion (Sala de Situação em Saúde, 2015). These data demonstrate the programme's importance and the need to coordinate it with production development policies, since rising demand has driven the increased production of generic medicines.

In turn, the Ministry of Health budget grew from R\$59 billion in 2006 to R\$100.5 billion in 2013, also in real terms. By 2013, the amount

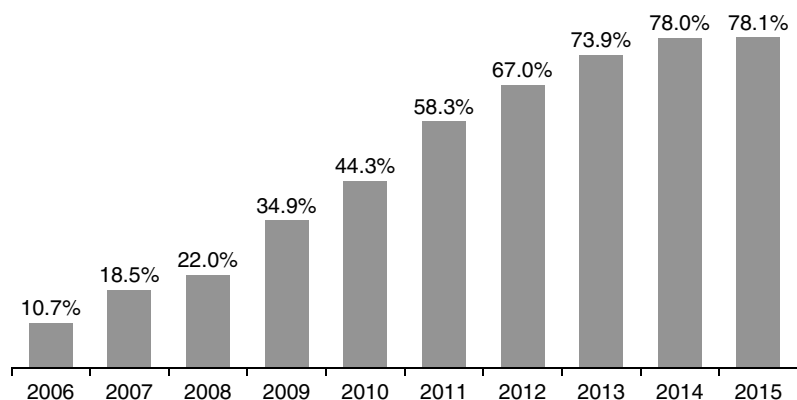


Figure 9.2 Percentage of municipalities covered by the PFPB, 2006–15

Source: Drawn by the authors from data from Sala de Situação em Saúde (2015), accessed 8 March 2015.

spent on medicines represented more than 10% of the total Ministry of Health budget. Public purchasing is responsible for 30% of the country's demand for medicine (Interfarma, 2014).

Strengthening public industrial production units has been a strategy to secure production in less intensive knowledge areas, such as generic products, in several Ministry of Health programmes. This approach also applies in more intensive knowledge areas, such as biological products, where the proportion of total Ministry of Health medicines expenditure has grown significantly, due to high prices, and contributed to the health sector's trade deficit. The Partnerships for Productive Developments (PDPs) were launched as a response to this.

Inter-sector coordination has enabled the creation of significant regulatory frameworks, which have tended to have a positive impact on the strategic sectors for the country's development. Significant features of these regulatory frameworks of support for innovation are Law 10973 of 2004 (Brasil, 2004c), known as the Innovation Law,⁴ and the Goods Law of 2005 (Brasil, 2005), which were important for the development of Brazil's health-related goods industry. Furthermore, the PDPs have been the object of inter- and cross-sector policies aimed at reducing external dependency, in favour of innovation and the extension of domestic capacity to produce strategic technologies, including biologicals, for SUS.

Partnerships for productive development (*Parcerias para o Desenvolvimento Produtivo*: PDPs)

The PDPs form part of the policies in the Greater Brazil Plan, which contains guidelines that focus on innovation and productivity growth in the Brazilian industrial complex. They are one of the components of the Programme for Investment in the Health Industrial Complex (*Programa de Investimento no Complexo Industrial da Saúde*: PROCIS). The latter was launched in 2012 to coordinate the national strategy for development and innovation in health through investment in public producers and in public infrastructure for production and innovation. It is thus aimed at strengthening Brazilian industry, providing the country with greater autonomy for the production of strategic SUS technologies.

There are currently 19 SUS public laboratories involved in PDPs. They are responsible for the production of medicines, serum and vaccines to meet the country's public health needs. However, many products are still imported from other countries, and gaps in domestic production as well as the high cost of medicines may hinder access. Through PROCIS,

the Ministry of Health has invested in public companies' infrastructure and workforce training (MS/DECIIS, 2015).

The partnerships are established between public drug production companies and the private production sector, aiming to absorb the technology to make new formulations. Thus, foreign companies with technological dominance commit to transferring to domestic companies the technology required to produce the medicine, as well as to produce within the country, to some degree, the active pharmaceutical ingredients (APIs) (the substance responsible for the treatment), over a five-year period. In return, the government guarantees exclusivity in procuring these products – at values below those quoted in the global market – over the same period. Until this point, since 1985, when the self-sufficiency programme in immunobiologicals was launched, there had been no other stimulus or public production investment programmes (Brasil, 2012 – Portaria nº 837/2012).

At the end of the technology transfer period, the domestic public laboratory will initiate autonomous production of the medicine in order to meet domestic demand. With production conducted inside the country, public laboratories will begin reducing dependence on imports (as illustrated by Figure 9.3), extending their competitive advantage and technological capacity.

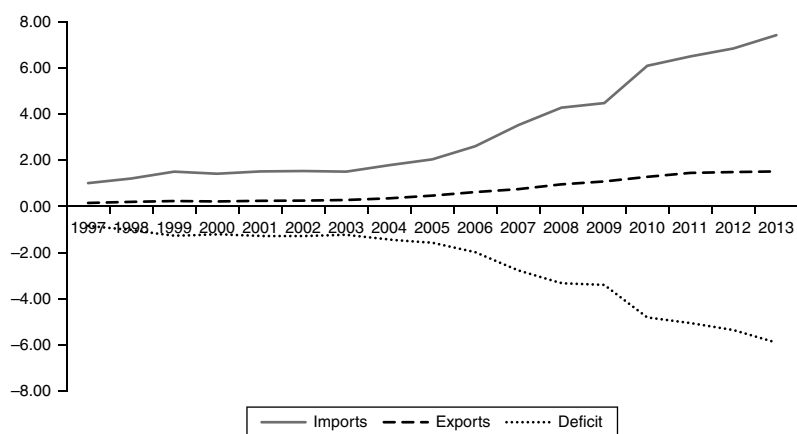


Figure 9.3 Pharmaceutical products: Balance of trade, Brazilian exports and imports (US\$ billion FoB)

Source: Drawn by the author from data from MDIC/Secex/Sistema Alice apud, INTERFARMA, 2014.

As well as generating significant savings for the Ministry (estimated at approximately R\$4 billion a year) and reducing the country's dependence on importing products (Figure 9.3), the partnerships signed thus far have also benefitted the population, since they guarantee the supply of essential medicines to the SUS network. In 2012, more than R\$250 million was invested in public pharmaceutical companies' infrastructure and workforce training – more than five times the average investment for the previous twelve years (R\$42 million). Between 2000 and 2011, total government investment was R\$ 512 million.

At the end of 2014, the Ministry of Health was involved in 104 product development partnerships, involving 19 public and 57 private laboratories. These agreements provide for the development of 101 products (66 medicines, 7 vaccines and 28 other health products).

Partnerships are focussed on the production of biological medicines, which have an average value significantly higher than traditional medicines and are principally used for the treatment of non-communicable diseases, such as various types of cancer and rheumatic problems. Although biological medicines represent approximately 5% of the medicines purchased by the Ministry of Health (measured by unit sales), they represent 49% of spending. Importing these products has been one of the main reasons for the increase in the health trade deficit, which leapt from approximately US\$1 billion in 1997 to more than US\$5 billion in 2013.

Reducing dependence on imported biopharmaceuticals by taking advantage of the predicted expiry of a series of product patents over the next few years may extend the population's access to treatments for those diseases for which the technology is demonstrably more effective than traditional medicine. In 2015, more than 25 biopharmaceutical products are available in SUS for the treatment of cancer, rheumatoid arthritis and other chronic diseases. Almost all are in the process of technology transfer to the national public companies.

In the specific case of cancer, the ability to introduce biopharmaceuticals for treatment has proven to be important in reducing inequality in access to this type of treatment. The Aragão et al. (2012) study demonstrated that biopharmaceuticals not incorporated into SUS were usually accessed via legal proceedings and that their implementation was restricted to such demands, prioritizing users of the private health system. In 2010, the federal government spent US\$3.4 million on responding to judicial demands related to the supply of biological therapies to treat cancer; since 2012, some of these have been incorporated into SUS. This signifies per capita spending of up to US\$183,300 in 2009 and 2010.

The public health system is responsible for the treatment of approximately 80% of cancer cases in Brazil. From 1999 to 2010, federal expenditure on chemotherapy alone rose in real terms from R\$780 million to more than R\$1 billion. In 2010, total expenditure, including spending on radiotherapy, surgery and radioiodine therapy, passed a landmark R\$1.5 billion, or US\$852 million (Aragão et al., 2014; MS, 2011). Spending on oncology medication represented more than 10% of total spending on medicines, with the largest burden coming from the acquisition of biological medication. With the exception of immunobiologicals (serum and vaccines) and one group of high-cost medicines aimed at a broad range of rare pathologies, oncology drugs accounted for the largest share of total Ministry of Health spending on medicines. Biopharmaceuticals, which will be produced through PDPs, currently represent R\$1.8 billion per year of Ministry of Health public procurement expenditure (MS/DECIIS, 2015).

In the case of cancer, considered here as an example, one needs to remember that treatment based on biological medicines is very costly, given that this is a high-complexity production category and, therefore, one with higher costs. Furthermore, it is more difficult to copy biological medicines once their patents have expired. Unlike chemicals, which may be copied as a whole, proteins are not amenable to identical copying; such copies are therefore biosimilar and require specific regulation. Moreover, companies in this sector have extremely high powers of negotiation, given the market concentration in a very small set of businesses.

Making use of public purchasing power and establishing policies to promote the domestic pharmaceutical industry, including public laboratories, are strategies to protect against the monopolistic practices exercised by the large pharmaceutical companies. These practices are made possible by a regime of intellectual protection highly favourable to economies in developed countries. In a sector in which the substitution of goods is highly limited, the persistence of such practices will certainly deepen social inequalities at both international and national level. From this perspective, policies that take into account the degree of market concentration may ensure the introduction of innovative technologies, while at the same time reducing inequalities in access to medicine.

Concluding reflections

Since the promulgation of Brazil's 1988 Constitution, significant progress has been made in improving the population's access to health

services, including to pharmaceutical health care. A series of legal and regulatory frameworks have been established in order to guarantee the free or subsidized provision of medicine to the population. To guarantee the domestic production of essential products, the Ministry of Health has become the country's central pivot in ensuring the local development of production capacity in order to develop technologies to meet SUS needs.

The Ministry of Health has managed to use its purchasing power to guide public and private investment in the interests of the SUS. This has reduced the main risk of technological innovation, which is the absence of a market. Product Development Partnerships have had huge success in transferring technology from the private sector (particularly the sector's large company leaders) to the public sector, which receives the technology and jointly develops the ingredients. Thus, even if production is shared with the private sector, the technology domain has moved to the public sector, as the regulatory framework indicates. However, the final results of the new model of partnerships established from 2012 should also be evaluated in the future, in relation to the ability to internalize the skills for production of APIs. Previous partnerships between private and public companies, as in the case of anti-retroviral drugs, allowed domestic production, but the country continued to depend on imports of the APIs.

What we observe is the construction of public policies to guide a range of health industry actors towards a social need, in this case the demand for medicine. To achieve this, the Ministry of Health has begun to coordinate policies traditionally regarded in Brazil as belonging to the economic sphere. Such orientation shifts the production logic of capitalist reproduction guided by the market, directing public and private investment towards the production of goods aimed at meeting SUS's priority health needs.

Such initiatives have led to successful actions, such as improved access to treatment for HIV/AIDS, cancer, diabetes, hypertension and a series of other diseases prevalent in the country, either through direct SUS provision or mediated through the PFPB in the form of free or low-cost distribution through the country's network of pharmacies. These initiatives in turn have contributed to the development of a domestic generic medicine industry capable of producing technologies to meet public and private health demands at competitive prices, as well as developing production capacity in more innovative areas, such as biopharmaceuticals.

The use of procurement powers and the policies to incentivize the domestic pharmaceutical industry, including public pharmaceutical

companies, are forms of protection from the monopolistic practices exercised by the large pharmaceutical corporations. Such practices are made possible through an intellectual protection regime which is extremely favourable to the economies of high-income countries. In a sector in which the substitution of goods is extremely limited, the persistence of such practices clearly deepens social inequalities at both national and international level.

However, huge challenges remain. The country remains a large-scale importer of pharmaceuticals and medicine. The construction of internal production capacity to reduce external dependency is a long-term process, involving heavy investment.

The production of generic medicines is extremely important in meeting domestic health needs, but it does not help to reduce the deficit because it is based on the import of active ingredients and, in certain cases, of formulations which are then combined. There is now a need for a policy that enables Brazilian companies to grow and acquire know-how in the development of generic medicines so they can make the leap towards the production of a more intensive local technology synthesis and broaden their portfolio of similar and innovative medicines for the market.

Notes

1. The research project that was the basis for this chapter received financial support from the National Council for Technological and Scientific Development (CNPq) through a grant to the Instituto Nacional de Ciência e Tecnologia em Saúde (CITECS) – National Institute of Science and Health Technology. The authors would like to thank Cressida Evans for the translation into English from the Portuguese version of this paper.
2. Federal Constitution law: Article 194: Social security encompasses a set of integrated actions by the public power and the civil society geared to assure the rights related to health, social security and social assistance. Article 196. Health is a right assured to all citizens and a state duty warranted through social and economic policies with the objective of reducing the risk of disease and other health impairment, and universal and egalitarian access to health actions for prevention, protection and recovery care (Brasil, 1988).
3. Law 12349/2010 and regulated by Decree 7546/2011.
4. Redrafted in Law no 12349, 2010.



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